

Appl. No. to be determined
Communication dated December 30, 2003
Preliminary Amendment and Request to Provoke Interference
Attorney Docket No.: 2183-4041.3US

REMARKS

Applicants present the following remarks pursuant to 37 C.F.R. § 1.607 and herein request that an interference be declared between the above-referenced application and U.S. Patent 6,500,662, issued December 31, 2002, to Calvert *et al.*

Claims 1 through 20 are to be canceled without prejudice or disclaimer. Any fee required but not submitted with this communication may be charged to deposit account no. 20-1469.

The present application is a continuation of co-pending application U.S. Serial No. 09/874,626, filed June 5, 2001, which is a continuation of Application Serial No. 09/297,535 filed October 12, 1999, now U.S. Patent 6,268,199, which was the National Stage of International Application No. PCT/NL97/00593 filed October 29, 1997, which claims the benefit of EP 96203024.3, filed October 30, 1996.

37 C.F.R. § 1.607:

Pursuant to Rule 607(a)(1), applicants identify U.S. Patent 6,500,662, issued December 31, 2002, to Calvert *et al.* (the '662 Patent) and submit claims for the same, or substantially the same, subject matter, within one year of the issuance of '662 patent in compliance with 35 U.S.C. § 135.

Proposed Count:

Pursuant to Rule 607(a)(2), the applicants propose the language of claim 21 of the instant application to be the count. 37 C.F.R. § 1.607(a)(2). The proposed count reads as follows:

An isolated polynucleotide molecule comprising a DNA sequence encoding an infectious RNA molecule encoding a United States strain PRRS virus.

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In the alternative, applicants propose the language of claim 22 of the instant application as the count, *i.e.*,

An isolated polynucleotide molecule comprising a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402.

37 C.F.R. § 1.607(a)(3):

Pursuant to Rule 607(a)(3), applicants identify claims 1 through 6 of U.S. Patent 6,500,662 to Calvert *et al.* as corresponding to the proposed count (or alternative proposed count).

37 C.F.R. § 1.607(a)(4):

Pursuant to Rule 607(a)(4), applicants identify claims 21 through 27 of the instant application as corresponding to the count. These claims read substantially as follows:

21. An isolated polynucleotide molecule comprising a DNA sequence encoding an infectious RNA molecule encoding a United States strain PRRS virus.

22. An isolated polynucleotide molecule comprising a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402.

23. A transfected cell comprising a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402, which transfected cell is capable of expressing the encoded PRRS virus.

24. An isolated polynucleotide molecule in the form of a plasmid, wherein said isolated polynucleotide molecule comprises a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402.

Appl. No. to be determined
Communication dated December 30, 2003
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Attorney Docket No.: 2183-4041.3US

25. An isolated infectious RNA molecule encoded by an isolated polynucleotide molecule, which infectious RNA molecule encodes a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402.

26. A recombinant PRRS virus encoded by an isolated polynucleotide molecule comprising a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402.

27. An isolated polynucleotide molecule comprising a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus wherein said PRRS virus comprises ORF7 protein of ATCC VR2332.

Applicants presently believe that the terminology "United States strain PRRS virus" as used in the proposed count and applicants' claim 21 would be the same or substantially the same as "a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence . . . [is] a sequence that hybridizes to the complement of SEQ ID NO:1 under highly stringent condition[s], wherein said highly stringent conditions comprise hybridization to filter-bound DNA in 0.5 M NaHPO₄, 7% SDS, 1 mM EDTA at 65° C., and washing in 0.1×SSC/0.1% SDS at 68° C" (as used in claims of the '662 Patent).

With respect to the alternative proposed count, applicants presently believe that the terminology "a DNA sequence encoding an infectious RNA molecule encoding a PRRS virus selected from the group consisting of PRRS virus strains ATCC VR 2332, ATCC VR 2385, ATCC VR 2386, ATCC VR 2429, ATCC VR 2474, and ATCC VR 2402" (as used in claims 22 through 26 of the instant application and in the proposed alternative count) would be the same as (or substantially the same as) "a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence . . . [is] a sequence that hybridizes to the complement of SEQ ID NO:1 under highly stringent condition[s], wherein said highly stringent conditions comprise hybridization to filter-bound DNA in 0.5 M NaHPO₄, 7% SDS, 1 mM EDTA at 65° C., and washing in 0.1×SSC/0.1% SDS at 68° C" (as used in claims of the '662 Patent).

Appl. No. to be determined
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Attorney Docket No.: 2183-4041.3US

All of the strains identified in the Markush grouping are U.S. strains of PRRSV. Also, at least the strain known as ATCC VR 2332 has significant sequence homology to SEQ ID NO:1 of the '662 Patent and would presumably hybridize to the complement of SEQ ID NO:1 under the "highly stringent conditions" identified in claim 1 of the '662 Patent.

With respect to applicants' claim 27, applicants submit that the claimed DNA having ORF7 of the U.S. strain known as ATCC VR 2332 would correspond to the proposed count(s).

37 C.F.R. § 1.607(a)(5):

Pursuant to Rule 607(a)(5), applicants point out the following portions of the applicants' application, which provide support for the presented claims.

Basis for applicants' claim 21 is found throughout the application. Specific basis for the claimed "DNA sequence" can be found in original claim 8, which depended indirectly from claims 5 and 1. Basis for the "United States strain of PRRS virus" language of claim 21, is provided, *inter alia*, at page 4, line 27 – page 5, line 2 of the application, which describes that the "immunological characterization and nucleotide sequencing of EP and US strains of PRRSV has identified minor antigenic differences within strains of PRRSV located in the structural viral proteins (Nelson et al., 1993; Wensvoort et al., 1992; Murtaugh et al., 1995)." Further basis can be found, *inter alia*, at page 4, lines 21-22 ("or ATCC VR 2332, 2385, VR 2386, VR 2429, and VR 2402") which describe various U.S. (or "North American") strains of PRRS.

Basis for applicants' claim 22 is found throughout the application. Specific basis for the claimed "DNA sequence" can be found in original claim 8, which depended indirectly from claims 5 and 1. Basis for the Markush group of applicant's claims, for example, claim 22, is found, *inter alia*, at page 4, lines 21-22 ("or ATCC VR 2332, 2385, VR 2386, VR 2429, and VR 2402") which describe various U.S. (or "North American") strains of PRRS. Further description is provided at page 4, line 27 – page 5, line 2 of the application, which describes that the "immunological characterization and nucleotide sequencing of EP and US strains of PRRSV has

Appl. No. to be determined
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identified minor antigenic differences within strains of PRRSV located in the structural viral proteins (Nelson et al., 1993; Wensvoort et al., 1992; Murtaugh et al., 1995).”

Basis for claim 23 can be found throughout the application, but specific basis can be found, for example, in original claims 2 through 4 and claim 18 of the application as-filed as well as in the detailed description (*e.g.*, pages 10 and 11).

Basis for claim 24 can be found throughout the application, but specific basis can be found, for example, on pages 13 through 14 of the application.

Basis for claim 25 can be found throughout the application, but specific basis can be found, for example, on pages 14 and 15 of the application.

Basis for claim 26 can be found throughout the application, but specific basis can be found, for example, in original claim 16 and on pages 14 and 15 of the application as-filed.

Basis for claim 27 can be found throughout the application, but specific basis can be found at page 7, lines 21-23 and page 24, lines 3-4.

37 C.F.R. § 1.607(a)(6):

Pursuant to Rule 607(a)(6) and 35 U.S.C. § 135(b)(1) the applicants have included claims 21 through 27 in the instant application within one year of the issue date (December 31, 2002) of U.S. Patent 6,500,662 B1 to Calvert *et al.*

Applicants note that the application eventually leading up to U.S. Patent 6,500,662 was apparently not earlier published. Therefore, 35 U.S.C. § 135(b)(2) should be inapplicable to the claims of the instant application, which is governed by 35 U.S.C. § 135(b)(1). As noted previously, the claims of the instant application are being filed within one year of the date on which the '662 patent was granted.

37 C.F.R. § 1.607(b):

Applicants note that pursuant to Rule 607(b), examination of the instant application is to “be conducted with special dispatch”.

Appl. No. to be determined
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Attorney Docket No.: 2183-4041.3US

37 C.F.R. § 1.607(c):

Pursuant to Rule 607(c), applicants submit that claims 1 through 6 of the '662 Patent substantially correspond to claims 21 through 27 of the instant application.

37 C.F.R. § 1.608:

Applicants' US effective filing date, October 29, 1997 (PCT International Application PCT/NL97/00593 (Publication WO 98/18933)) predates by more than one year the December 22, 1998 filing date of U.S.S.N. 60/113,345, the earliest claimed priority date of U.S. Patent 6,500,662 B1 to Calvert *et al.* Accordingly, should an interference be declared, applicants are entitled to judgment relative to Calvert *et al.* and the showing of Rule 608 should be inapplicable to the instant matter.

Conclusion

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the number given below.

Respectfully submitted,



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